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INDIANA UNIVERSITY
OFFICE OF THE VICE PRESIDENT
FOR RESEARCH

April 27, 2018

Brent Morse, D.V.M., DACLAM
Director, Division of Compliance Oversight
OLAW/NIH
RKL 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982
olawdco@mail.nih.gov

RE: Notice of Non-compliance for Assurance D16-00584 (A4091-01): Indiana University School of Medicine – Indianapolis.

Dear Dr. Morse:

This letter reports a new incident of non-compliance with PHS Policy and the Guide for the Care and Use of Laboratory Animals at the Indiana University School of Medicine for IACUC protocols covering laboratory mice.

This issue was discussed with the IACUC, and the incident and their determination are described below.

The committee discussed a report regarding three weaning mice which were found dead without food. The PI's lab staff failed to provide food at the time of weaning, and LARC husbandry care staff failed to notice the mice were without food.

To ensure this will not occur in the future, the PI held a lab meeting to address the concern and provide re-training. The PI stated that the lab has planned additional measures, such as double-checking all animals, to ensure that this will not occur again.

After significant time in deliberation and based on their understanding of the facts presented, federal regulations, and expectations, the IACUC committee members determined that this issue qualifies as a concern that should be reported to OLAW and the funding agency.

This activity is supported by PHS funds (2R01DK063114). The program official is copied on this letter.

Please do not hesitate to contact me if you have any questions after receiving this letter.

Sincerely yours,

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Fred H. Cate
Vice President for Research
Distinguished Professor and C. Ben Dutton Professor of Law

cc:

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Robert Considine, Ph.D. (School of Medicine, IACUC Chair)
Debra Hickman, D.V.M., M.S., DACLAM (Director, Laboratory Animal Resource Center)
Megan Losh, M.P.A., CPIA (School of Medicine IACUC Director)

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Paul Kimmel (NIH Program Official: kimmelp@niddk.nih.gov)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, May 01, 2018 6:14 AM
To: Losh, Megan
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: non-compliance reports - D16-00584

Thank you for these reports, Ms. Losh. We will send responses soon.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: Losh, Megan [mailto:meglosh@iu.edu]
Sent: Monday, April 30, 2018 4:06 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)@iu.edu>; Considine, Robert V. <rconsidi@iu.edu>; Hickman, Debra <hickmand@iupui.edu>
Subject: non-compliance reports - D16-00584

Dear OLAW –

Please find attached reports for Indiana University School of Medicine – Indianapolis (D16-00584). Please let me know if you have any questions.

Thank you,

Mégan Losh, MPA, CPIA
IACUC Director
School of Medicine IACUC
Office of Research Compliance
Office of Vice President for Research
Indiana University
meglosh@iu.edu
(b) (6)